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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,445	01/09/2004	Robert A. Ganz	021827-000140US	7989
7590 03/17/2006 CHRISTIANA STATE (REG. NO. 52,045) WILSON SONSINI GOODRICH AND ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304			EXAMINER VRETTAKOS, PETER J	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/754,445

Applicant(s)

GANZ ET AL.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 28-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6-8-5, 2-3-5, 4-26-4.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

**The action is non-final. The Examiner changed the statement that “intended use language has no patentable weight” to “intended use language has little patentable weight” in the below rejections.**

Claims 28-49 are pending.

This application is from a family of applications and/or patents involving esophageal tissue treatment some of which are:

- 1) 10/426,923 Ex. Vrettakos AU3739
- 2) 10/370,645 Ex. Vrettakos AU3739     At Appeal as of 3-15-06.
- 3) 10/754,444 Ex. Toy AU3739

**The Examiner reserves the right to impose a species restriction in a future action.**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34-38 recite the limitation "balloon". There is insufficient antecedent basis for this limitation in the claims. Claim 33 (on which 34-38 depend) alternatively depends upon claims 28 and 29, neither of which disclose a "balloon".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 28, 29, 33 and 40-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards (6,405,732).**

Edwards et al. (6,405,732) discloses:

28. A system (10) *for treating mucosal tissue (intended use)* in an esophagus (6), said system comprising: an elongated member (18); an energy delivery structure (20) deployable (it is a "balloon, frame or cage" – language from Applicant's specification) from the elongated member (18) and adapted to deliver energy (col. 11:27-50; treatment electrodes 22, col. 7:48-53; 88) to at least a portion of a circumferential section (see patented claim 11) *of the mucosal lining (intended use language)* of the esophagus (6); and means for delivering energy (22, 88) through the delivery structure under conditions selected *to initiate regrowth* (intended use) of a

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mucosal layer *without substantial injury to a submucosal layer* (intended use) underlying the mucosal layer. (Preservation of the submucosal layer is suggested in patented claim 20. Also note feedback control is disclosed in patented claim 26.)

Note: treating mucosal tissue is intended use language. A recitation of the intended use of the claimed invention must result in a *structural difference* between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Office contends that at least one of the Edwards' embodiments is structurally capable of treating mucosal tissue in the esophagus.

29. A system as in claim 28, wherein the energy delivery structure comprises an expandable structure (20, figure 11a) deployable from the elongated member.

30. A system as in claim 29, wherein the expandable structure comprises an expandable balloon (55, figure 5b).

31. A system as in claim 30, wherein the balloon is non-distensible and dimensionally stable (as a result of element arms 44).

32. A system as in claim 30, wherein the balloon is elastic (inherent).

35. A system as in claim 34, wherein the electrodes are aligned axially on the balloon. See figure 18b.
36. A system as in claim 34, wherein the electrodes are aligned circumferentially over the balloon. See figures 18a,c.
37. A system as in claim 33, wherein the balloon includes electrodes of a common polarity (col. 11:65-67) formed over at least a portion of its exterior surface.
38. A system as in claim 33, wherein the balloon includes electrodes of a common polarity formed over at least a portion of its **inner** (figure 11a) surface.
39. A system as in any of claims 30 to 32, wherein the **balloon** is inflatable with a conductive medium to form a monopolar electrode.
33. A system as in any of claims 28 to 32, wherein the energy delivery structure further comprises an electrode (22, treatment and/or mapping electrodes, col. 7:50-53) array.
40. A system as in claim 29, wherein the expandable structure comprises a frame (50, figure 4b) deployable from the elongated member (18) and an electrode array (22) formed over at least a portion of the frame.

41. A system as in claim 40, wherein the frame comprises an arcuate surface (clearly depicted in figure 4b) which carries the electrodes (22) to engage a partial section of the circumference of the esophagus.

42. A system as in claim 41, wherein the frame comprises two oppositely facing arcuate surfaces. Again, clearly depicted in figure 4b.

43. A system as in claim 28, wherein the energy delivery structure comprises a heating structure. See col. 11:27-50.

44. A system as in claim 43, wherein the heating structure comprises a radiation heat source. See col. 11:27-50, especially line 40.

45. A system as in claim 44, wherein the energy delivery structure further comprises a pair of expandable centering elements (20 in figure 3) disposed distally and proximally of the radiation heat source (22,88; col. 11:27-50, especially line 40).

46. A system as in any one of claims 43 to 45, wherein the radiation heat source is a filament, spherical radiator, cylindrical radiator, or polygonal radiator. In figures 3 and 4b element 22 (heat source) is a cylindrical.

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47. A system as in claim 28 wherein the energy delivery means comprises a photonic source. See col. 11:27-50.

48. A system as in claim 28, wherein the energy delivery means comprises a radiofrequency power supply. See col. 11:27-50.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 34 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (6,405,732).**

Edwards is silent regarding *specific* electrode spacing dimensions, However, the patent discloses alternate electrode spacing and its relation to the spacing's effect on lesion creation (col. 14:33-47) thereby making electrode spacing "no more than 3mm" obvious and easily determined through routine experimentation. The motivation to perform the experiments would be to understand the effects of the size of the spacings on lesion creation.

34. A system as in claim 33, wherein the electrode array comprises bipolar



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electrode pairs (col. 11:65 through col. 12:11; elements 88 are equated to elements 22) formed over at least a portion of the outer surface of the balloon (see figure 11a), wherein the **spacing between the electrodes is no more than 3 mm.**

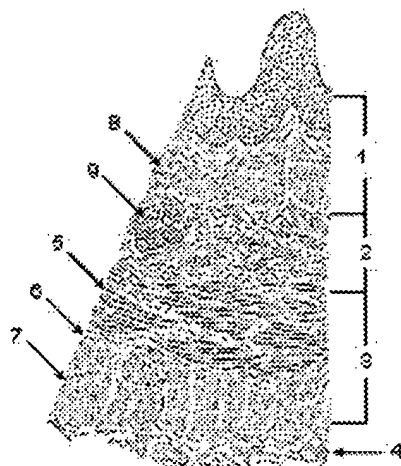
49. A system as in claim 48, wherein the radiofrequency power supply is adaptable to deliver an energy dosage in the range from 1 J/cm.<sup>2</sup> to 50 J/cm.<sup>2</sup> over a time period less than 5 seconds. The parameters would be obvious in light of routine experimentation.

Further, the parameters are intended use. A recitation of the intended use of the claimed invention must result in a *structural difference* between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Office contends that at least one of the Edwards' embodiments is structurally capable of the claimed parameters.

### ***Response to Arguments***

Applicant's arguments with respect to claims 28-49 have been considered but are moot in view of the new ground(s) of rejection.

For future reference:



1. Mucosa
2. Submucosa
3. Muscularis
4. Adventitia
5. Striated muscle
6. Striated and smooth
7. Smooth muscle
8. Lamina muscularis mucosae
9. Esophageal glands

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 28-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-89 of copending Application No. 2004/0215235. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim expandable energy delivery catheters used in the esophagus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 28-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-96 of copending Application No. 2004/0087936. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim expandable energy delivery catheters used in the esophagus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 28-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 2005/01715254. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim expandable energy delivery catheters used in the esophagus.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The Applicant should file terminal disclaimers in the other Applications, as well.

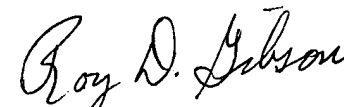
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos  
March 10, 2006



  
ROY D. GIBSON  
PRIMARY EXAMINER